Supreme Court, U.S.
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In the

Supreme Court of the United States

TORPHARM, INC.,

Petitioner,

v.

GENPHARM, INC., MYLAN LABORATORIES, INC., NOVOPHARM LTD., NOVOPHARM USA, INC., and GRANUTEC, INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a secret sale between third parties gives rise to an "on sale" bar as against an independent inventor who in good faith discloses the invention through a patent.

CORPORATE DISCLOSURE STATEMENT

TorPharm, Inc. is a privately-held Canadian corporation.

It has no parent company and there are no publicly held companies owning 10% or more of its stock.

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PETITION FOR WRIT OF CERTIORARI

Petitioner, TorPharm, Inc. ("TorPharm"), respectfully petitions this Court for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit. TorPharm seeks reversal of the decision of the Court of Appeals that affirmed the judgment of the United States District Court for the Eastern District of North Carolina holding invalid claim 1 of TorPharm's U.S. Patent 5,523,423.

OPINIONS BELOW

The unpublished order of the United States Court of Appeals for the Federal Circuit affirming the judgment of invalidity of claim 1 of TorPharm's patent is set forth in the Appendix, at App.1. The Court of Appeals order denying TorPharm's Petition for Rehearing and Suggestion for Rehearing En Banc is set forth in the Appendix, at App. 18.

The unpublished Order and Opinion of the United States District Court for the Eastern District of North Carolina is set forth in the Appendix, at App. 3.

JURISDICTION

The Court of Appeals affirmed the holding of invalidity of claim 1 of TorPharm's patent on May 17, 2000 (App. 1) and denied TorPharm's Petition for Rehearing and Suggestion for Rehearing En Banc on July 11, 2000 (App. 18). This petition is timely filed within 90 days of the latter order.

TorPharm invokes this Court's jurisdiction pursuant to 28 U.S.C. § 1254(1) (1988).

CONSTITUTIONAL PROVISION INVOLVED IN THIS CASE

United States Constitution Article I, Section 8, Clause 8:

> The Congress shall have power * * * to promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries * * *

STATUTE INVOLVED IN THIS CASE

35 U.S.C. § 102 – Conditions for patentability; novelty and loss of right to patent.

> A person shall be entitled to a patent unless –
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,
>
> * * *

STATEMENT OF THE CASE

BASIS FOR FEDERAL JURISDICTION

The district court had jurisdiction under 28 U.S.C. §§ 1331, 1338(a) because the civil action arose under an Act of Congress relating to patents.

The district court's jurisdiction also was based on 28 U.S.C. §§ 2201 and 2202 because Respondents Genpharm, Inc., Mylan Laboratories, Inc., Novopharm, Ltd., and Novopharm U.S.A., Inc., sought a declaration of non-infringement and invalidity of TorPharm's patent.

STATEMENT OF FACTS

In 1995, the assignors to Petitioner TorPharm, Inc. filed a U.S. patent application for their invention of an improved "form of Form 1 ranitidine," an ulcer medication, which led to the issuance of U.S. Patent 5,523,423 (the '423 patent). (A00094-97).[1] After the issuance of the '423 patent, Respondents Genpharm, Inc., Mylan Laboratories, Inc., Novopharm Ltd., Novopharm USA, Inc., and Granutec, Inc. (collectively "Novopharm") instituted the lawsuit below, seeking to invalidate the '423 patent. (A00066-A00145). Three separate actions were consolidated at the district court and on appeal.

In 1998, Novopharm issued a discovery subpoena to a non-party, Geneva Pharmaceuticals, Inc. ("Geneva"), and obtained certain confidential documents under protective

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[1] All "A" citations are to the parties' joint appendix filed in the Court of Appeals.

order. (A00305-A00307). The confidential "Geneva documents" (A00198-A00246) suggested that in 1992, three years prior to the filing of TorPharm's patent application, yet another non-party, Interchem Corporation ("Interchem"), had secretly sold to Geneva a bulk shipment of ranitidine for "developmental" purposes, *i.e.*, for formulation and testing as required for an abbreviated new drug application to be submitted to the FDA. (*E.g.*, A00198, A00200). On the basis of the Geneva documents, Novopharm moved for summary judgment that claim 1 of TorPharm's '423 patent was invalid under the on-sale bar. (A03820 & n.2). Novopharm stipulated for purposes of its motion that the Interchem-Geneva transaction was "secret and confidential" and "not made in the public realm." (A00366 n.2, A00295-A00298). The district court granted Novopharm's motion and entered summary judgment. (A00001-A00012; A05007-A05008).

On appeal, the U.S. Court of Appeals for the Federal Circuit affirmed without opinion. (App. 1). TorPharm filed a petition for rehearing and suggestion for rehearing en banc, on the issue presented here, which was denied. (App. 18).

REASONS FOR GRANTING THE WRIT

I.

THE FEDERAL CIRCUIT'S HOLDING THAT A SECRET SALE BETWEEN THIRD PARTIES GIVES RISE TO AN ON-SALE BAR CONFLICTS WITH THE PRINCIPLES ANNOUNCED IN *PFAFF* AND FAILS TO RECONCILE THE FEDERAL CIRCUIT'S HOLDING IN *MAHURKAR*

Since 1793, Congress has fulfilled its mandate to provide for the grant of patents to inventors. *See* U.S. Const. art. 1, § 8, cl. 8. Patents add "the fuel of interest to the fire of genius." Abraham Lincoln, Lecture on Discoveries and Inventions (1859), quoted by the Hon. A. Gajarsa, *How Much Fuel to Add to the Fire of Genius?*, 48 AM. U. L. REV. 1205, 1207 & nn. 4 & 6 (1999). Thus, Section 102 of 35 U.S.C. states that an inventor *shall* be entitled to a patent *unless* one of the specified statutory bars applies, *e.g.*, the "public use or on sale" bars of 35 U.S.C. § 102(b) (1984).

The Purpose Of The On-Sale Bar, As This Court Stated In *Pfaff*, Is To Protect The Public's Right To Retain "Knowledge Already In The Public Domain" And The Inventor's Right To Control "Whether And When" He May Patent His Invention

In *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), this Court observed that the "main object" of the patent laws "'was to promote the progress of science and useful arts' . . . by giving the public . . . the thing invented, at as early a period as possible; having a due regard to the rights of the inventor." *Id.* at 19. The "public use or on

sale bars" effectuate this main object: First, by requiring a patent applicant to file, and thus to disclose the invention to the public, promptly upon commercially exploiting his invention, *id.* at 19; second, by preventing the grant of a patent where "the public were already in possession and common use of an invention," *id.* at 22-23.

In *Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877), the Court observed that the "public use or on sale" bars were intended, first, to prevent an inventor from profiting by "undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law," *id.* at 137, and, second, to prevent the grant of a patent on an invention already in "general use," *i.e.*, in the public domain, *id.* at 135.

In *Andrews v. Hovey*, 123 U.S. 267, 8 S. Ct. 101 (1887), the Court analyzed the "public use or on sale" bars and found the same two purposes: First, "to require the inventor to see to it that he filed his application within two years from the completion of his invention," and, second, to fulfill the "evident intention of congress" to prevent the issuance of a patent "after an invention had for a long period of time been in public use . . . whether the inventor had or had not consented to or allowed the public use." *Id.* at 274, 8 S. Ct. at 105.

While these cases were not decided under the present patent statute, it is beyond dispute that they reflect the fundamental principles behind the on-sale bar. Thus, in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998), the Court reaffirmed the dual purposes of the "public use or on sale" bars: "The patent laws . . . seek

both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Id.* at 65, 199 S. Ct. at 310.

Pfaff cited with approval each of the above-cited Supreme Court precedents as well as *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), in which Judge Learned Hand synthesized the authorities into two lines of "public use or on sale" cases. The first line involves the "inventor's competitive exploitation" of the invention; the second involves the contribution that had previously been made to the "art," that is, the prior art already in the public domain. *Id.* at 520.

Pfaff, the culmination of the first line of cases, drew a bright line at an inventor's commercial exploitation, holding as follows:

> We conclude, therefore, that the on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. * * * Second, the invention must be ready for patenting.

525 U.S. at 67, 119 S. Ct. at 311-12.

Here, the courts below found that there had been a commercial sale of a ready-to-patent product. But the lower courts erred in invalidating TorPharm's U.S. Patent 5,523,423 (the '423 patent), because the sale was

between two strangers to the inventor, *cf. Pfaff*, 525 U.S. at 67, 119 S. Ct. at 311-12 (inventor's commercialization), *and* the strangers' secrecy kept the invention from the public, *cf. Abbott Laboratories v. Geneva Pharmaceuticals*, 182 F.3d 1315, 1317-19 (Fed. Cir. 1999) (third party's non-secret sale injected technology into public domain). The lower courts misapplied *Pfaff* to a non-inventor secret sale invoking neither of the two purposes of the on-sale bar which inform the meaning of that term of art.

The Court Of Appeals' Decision Below Thwarts The Principles Announced In *Pfaff*

In the lower courts, Respondents relied principally on two lines of inapposite on-sale cases. One line—exemplified by *Abbott Laboratories v. Geneva Pharmaceuticals*, 182 F.3d 1315 (Fed. Cir. 1999)—involved a third-party, non-secret sale; because the public had knowledge of the invention, the inventor could properly be charged with notice that the claimed compound was already on the market. This line follows the rationale of the public-use and publication cases, where the invention has been made known to the public. *See, e.g., Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986) (rejecting public-use bar where inventor's use was "private"); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 936-37 (Fed. Cir. 1990) (holding patent challenger did not prove by clear and convincing evidence that "anyone could have had access to the documents disclosing the invention by the exercise of reasonable diligence").

The other line of on-sale cases—*Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304 (1998), *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326 (Fed. Cir. 1998), and *Brasseler U.S.A. I., L.P. v. Stryker Sales Corp.*, 182 F.3d 888 (Fed. Cir. 1999)—is not concerned with public knowledge, but addresses commercialization by the inventor or those in privity with him. These cases fall within the rationale stated in *Pfaff* that "[a]*n inventor* can both understand and control the timing of the first commercial marketing of his invention." 525 U.S. at 67, 119 S. Ct. at 311 (emphasis added).

Neither of these two lines of on-sale cases applies here, where it is undisputed that the alleged sale between non-parties Geneva and Interchem did not involve the inventors of the '423 patent, and those inventors, as Respondent Novopharm admitted, "did not even know about the so-called 'developmental' work by Geneva." (Novopharm Appeal Br. at 14.) *Cf. Pfaff*, 525 U.S. at 67, 119 S. Ct. at 311 ("[a]n inventor can both understand and control the timing of the first commercial marketing of his invention"). Novopharm stipulated for purposes of its summary judgment motion that the Interchem-Geneva transaction was "secret and confidential" and "not made in the public realm." (A00366 n.2, A00295-A00298). *Cf. Abbott*, 182 F.2d at 1317-19 (third party non-secret sale injected technology into public domain). Indeed, there was no way that either the inventors or the public could have known about the Geneva experimental work, which was undertaken solely for the purpose of filing an abbreviated new drug application to be submitted to the FDA. There was no commercial sale to the public at large—ever.

The Federal Circuit's Decision Below Conflicts With The Federal Circuit's Previous Decision In *Mahurkar*

In *Mahurkar v. Impra*, 71 F.3d 1573 (Fed. Cir. 1995), the Federal Circuit held that an inventor's sale of two prototype catheters did not invoke the on-sale bar because the sale "did not place the invention in the public domain or lead the public to believe that the device was freely available." *Id.* at 1577. The Federal Circuit's order in the case at bar is in direct conflict with *Mahurkar*, because the sale here (by third parties, not the inventor) was just as secret.[2] *Pfaff*, which was a "ready for patenting" inventor-sale case, did not address this issue.

In sum, neither *Pfaff* nor any other authority can bring the on-sale bar down on the head of an inventor who knew nothing of any secret sale between third parties, particularly where, as here, there was no "knowledge already in the public domain." *Pfaff*, 525 U.S. at 65, 199 S. Ct. at 310.

To resolve the conflict with the principles announced in *Pfaff* and the conflict with *Mahurkar*, the Court should grant certiorari.

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[2] The Federal Circuit's recent decision in *Zacharin v. United States*, 213 F.3d 1366 (Fed. Cir. 2000), did not involve the question presented by this Petition as it was not a secret sale.

CONCLUSION

Wherefore, for the foregoing reasons, Petitioner TorPharm, Inc. respectfully prays that its Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit be granted and that the Federal Circuit be ordered to reverse the district court's judgment and to remand the consolidated cases for adjudication on their merits.

Respectfully submitted,

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